Deloitte.

Life Sciences International Summit

David Hearn

Head of Deloitte Consulting Ireland

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Deloitte's Life Sciences Practice

Deloitte Capabilities

- Strategy & Operations
- Regulation and Corporate Governance
- Technology Solutions and Implementation
- Corporate Finance
- Human Resources
- Audit and Assurance
- Security and Controls
- Tax

Working With Industry Leaders

- 85% of Fortune 1000 LS&HC companies
- 10 of the 10 largest pharmaceutical manufacturers
- 10 of the 10 largest medical equipment manufacturers
- 10 of the 10 largest biotechnology companies

Recognition

The #1 Life Sciences & Health Care Consulting Organization

KENNEDY INFORMATION
RESOURCES FOR PROFESSIONALS SINCE 1970

The Largest Health Care Management Consulting Organization

MODERN HEALTHCARE ONLINE

Global life sciences industry issues in 2014
Aging and Demographics

Aging population

- The aging population is a shared, long-term trend in markets including Western Europe, Japan, and surprisingly China.
- Overall life expectancy is expected to increase from an estimated 72.6 years in 2012 to 73.7 years by 2017

Demographic trend

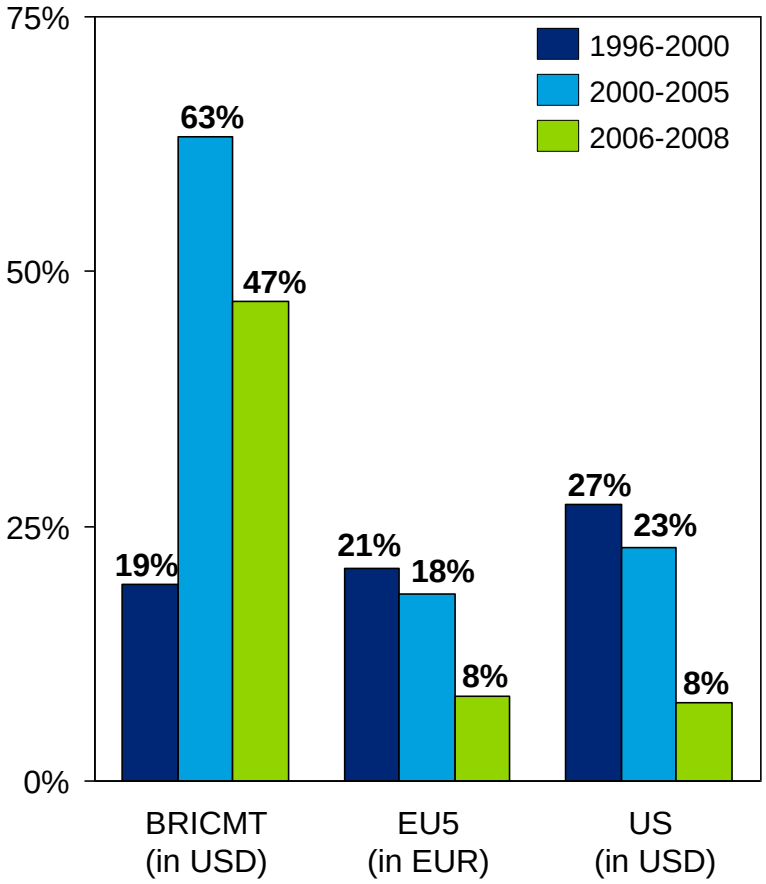
The biggest shared demographic trend is the spread of chronic diseases, which is due to:

- Aging population
- Sedentary lifestyles
- Diet changes
- Rising obesity levels

BRICMT makes its mark …

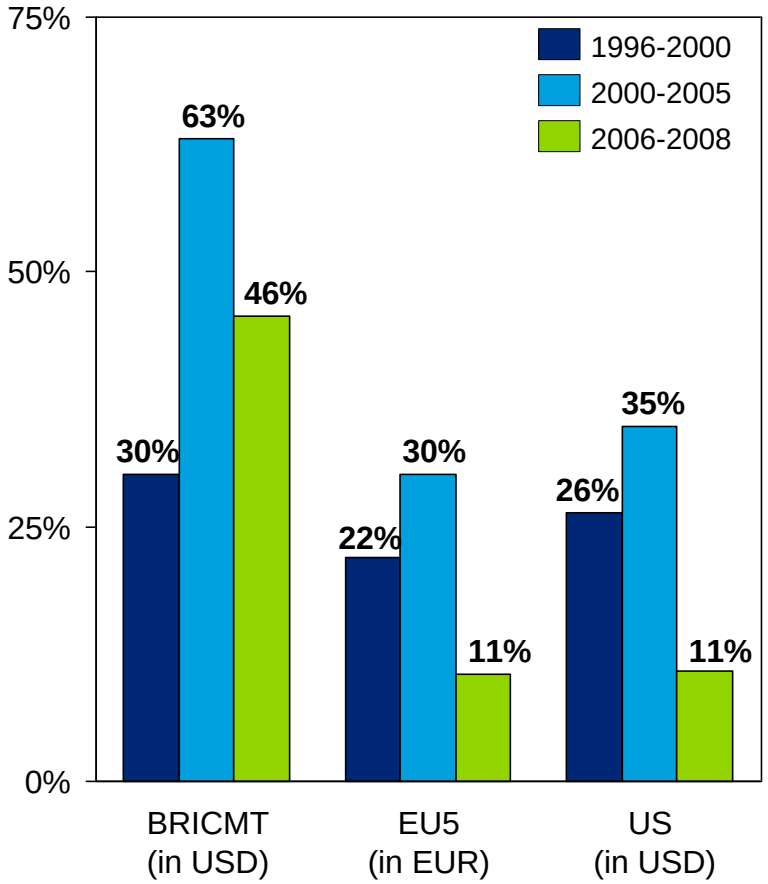
Growth of GDP by Regions

(1996- 2008)



Growth of Total Healthcare Expenditures by Regions

(1996-2008)

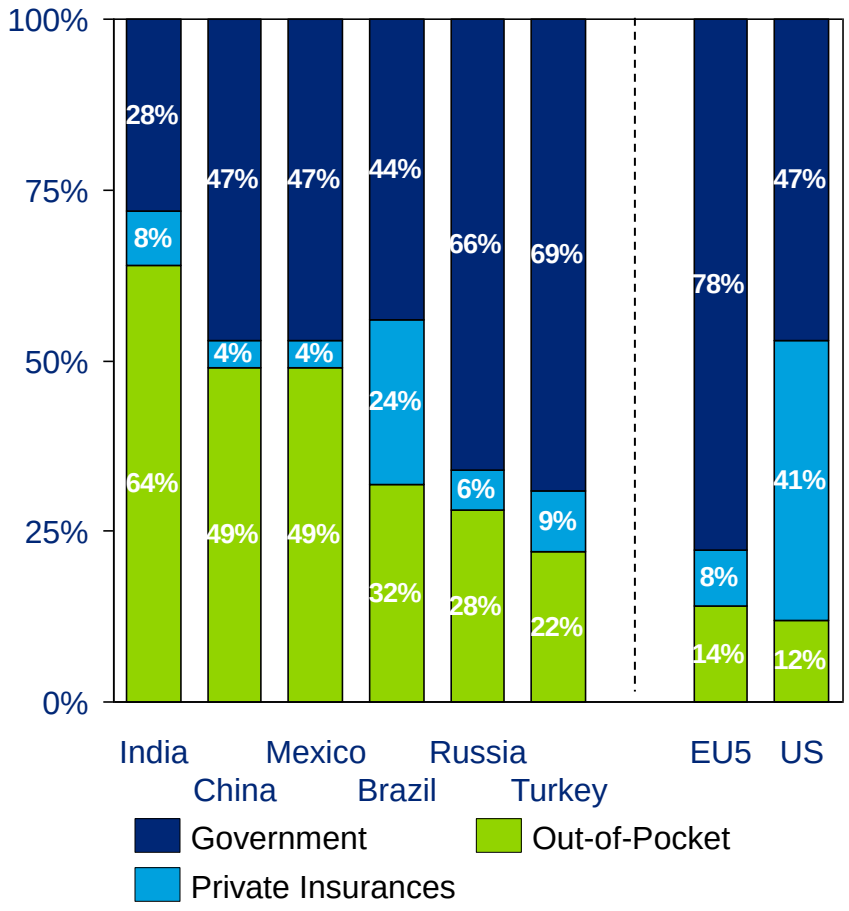


Note: BRICMT = Brazil, Russia, India, China, Mexico, Turkey

… but have very different healthcare structures

Sources of Funding for Healthcare Expenditures by Country

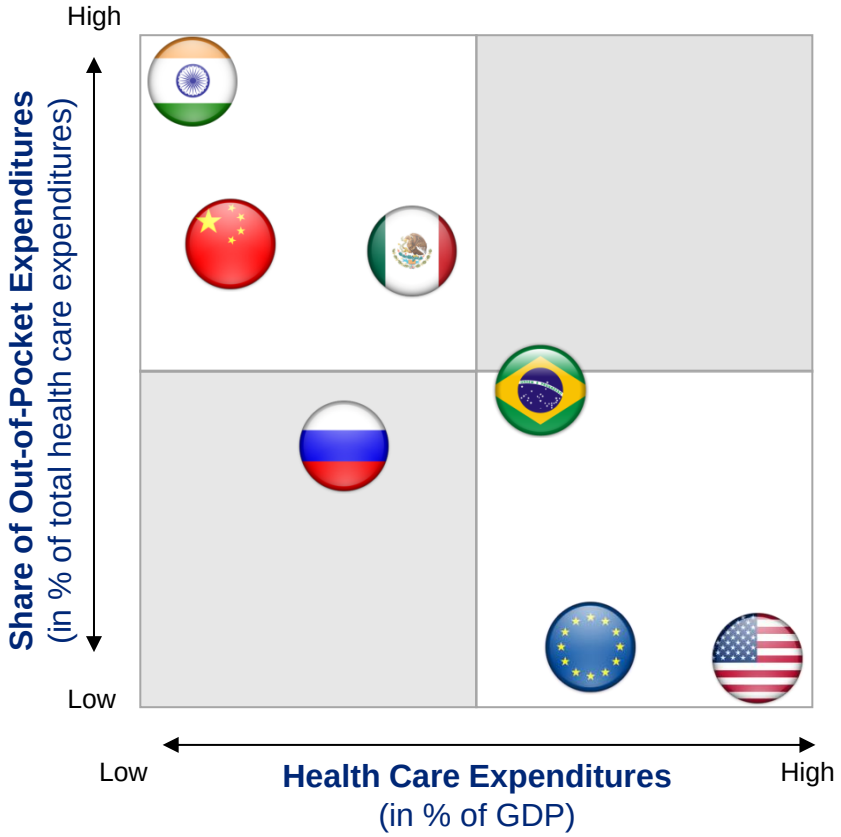
(2008, % of total health care expenditures)



Note: BRICMT = Brazil, Russia, India, China, Mexico, Turkey

Share of Out-of-Pocket Expenditures by Total Healthcare Expenditures in % of GDP per Country

(2008)



Global life sciences industry issues in 2014

Delivering innovation and value

Patent cliff

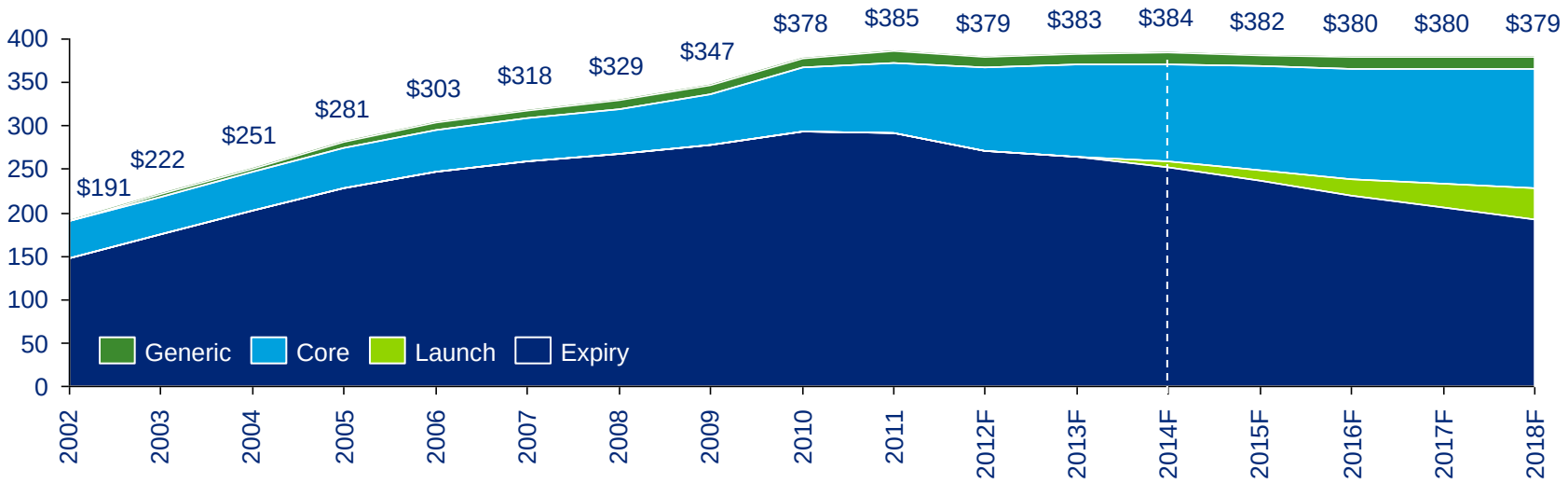
- The patent cliff is now at its steepest point. In 2012, $38 billion of worldwide prescription drug sales were lost as a result of expired patent protection.
- The risk continues as governments and other payers intensify efforts to maximize savings from patent expirations by promoting the use of generics.
- Many countries across the world have introduced programs to encourage generic use, including India and most European countries.

Biosimilars

- Engineering copies of high-priced biotech drugs offers another growth opportunity for generics producers.
- The global market for biosimilars grew by 44 percent in 2011, to $2.5 billion, and is expected to rise to $3.6 billion by 2016, with the fastest growth in Asia-Pacific.
- The U.S., the European Union, Japan, and other countries have created regulatory pathways for biosimilar products, although U.S. health care reform also extended the patent protection on biotech drugs to 12 years, potentially slowing U.S. biosimilars growth.

Patent expirations are only marginally replenished by upcoming launches...

Sales of top drugs (c. 80% of revenues) by lifecycle stage (top 12 companies), 2002-18F, $bn



Selected top brand-name drugs with patent expirations from 2013-2018

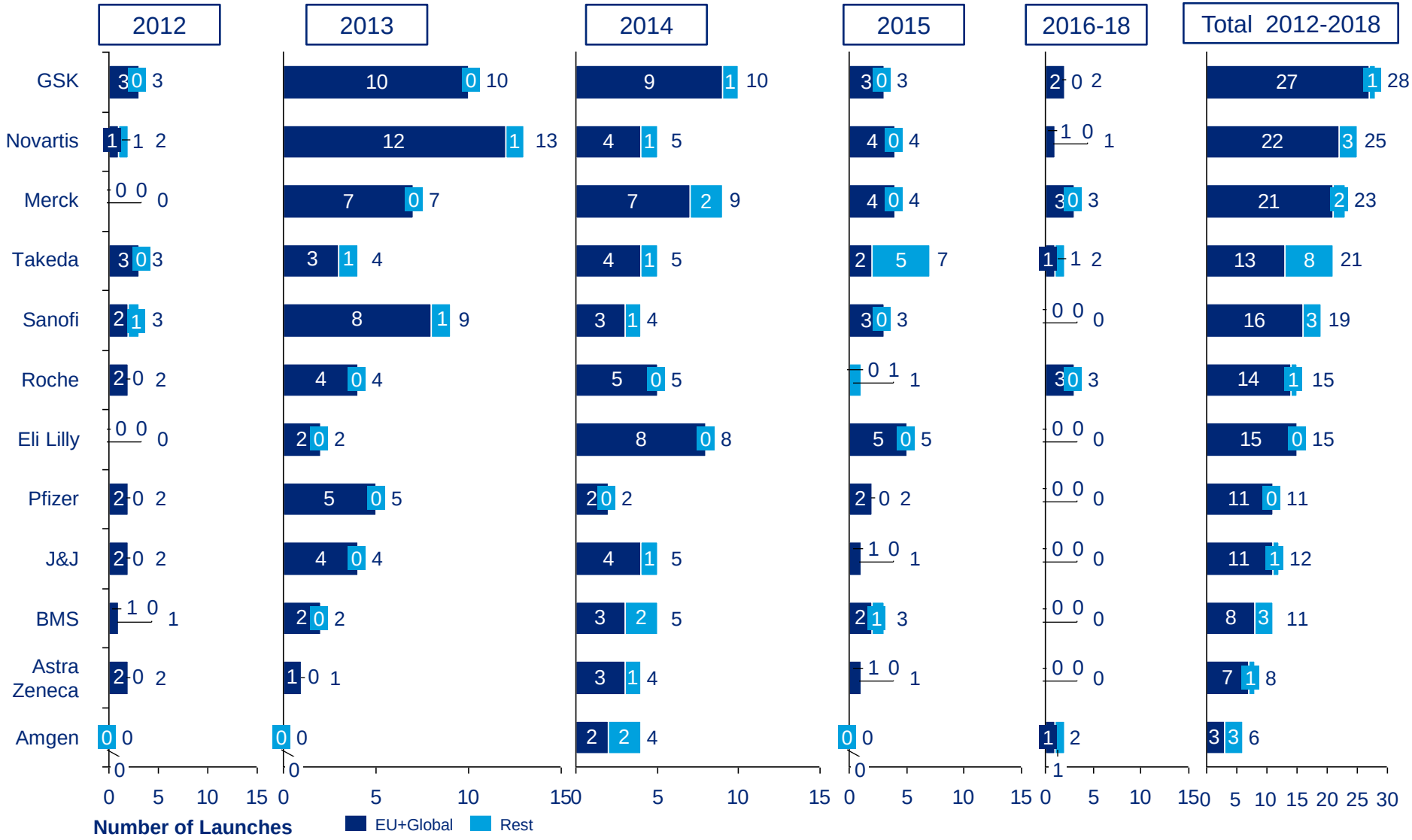
2013	2014	2015	2016	2017	2018
Cymbalta (Eli Lilly)	Nexium (AstraZeneca)	Gleevec (Novartis)	Strattera (Eli Lilly)	Reyataz (BMS)	Erbitux (BMS / Eli Lilly / Merck)
Humalog (Eli Lilly)	Vytorin (Merck)	Avodart (GSK)	Zetia (Merck)	Seroquel XR (AstraZeneca)	Orlistat (Roche / GSK)
Rebif (Merck)	Evista (Eli Lilly)	Lovaza (GSK)	Crestor (AstraZeneca)	Kaletra (Abbott)	
Aciphex (J&J)	Renagel/Renvela (Sanofi)	Abilify (BMS)	Advair (GSK)		
Xeloda (Roche)		Zyvox (Pfizer)	Humira (Abbvie)		
Neupogen (Amgen)		Emend (Merck)			

Source: Datamonitor; Monitor Deloitte Analysis

Note: Analysis encompasses the top 12 publicly-listed research-based pharmaceutical and biotechnology companies measured by 2008-09 R&D spend: Amgen, AstraZeneca, BMS, Eli Lilly, GSK, J&J, Merck, Novartis, Pfizer, Roche, Sanofi and Takeda; 2012-18 data are forecasts based on analyst consensus; This analysis only includes sales from top-selling drugs within the cohort so only reflect c. 80% of total revenues; *Generics* – drugs released or to be released as copies of drugs without patent protection; *Core* - patented drugs that neither launch nor expire between 2011-18; *Launch* - patented drugs launching between 2011-18; *Expiry* – patent expired drugs or patented drugs expiring between 2011-18

Multiple, smaller launches

Example: Pharma Launches



Source: Companies pipelines

Global life sciences industry issues in 2014

Delivering innovation and value

Sales revenue

Life sciences companies have adopted a multipronged approach to cope with the current and anticipated drop in sales revenue:

- Cutting costs and staff.
- Engaging in joint ventures and mergers and acquisitions (M&A) to share R&D risk and improve their product portfolio.
- Expanding in emerging markets.
- Recalibrating business models and research priorities; and using real-world evidence and emphasizing a product's clinical, safety, and economic impact (e.g., comparative effectiveness) to articulate their value proposition by identifying new ways to demonstrate product value.

R&D

- Life sciences R&D portfolio management is transitioning from its traditional vertically integrated scientific R&D model to one that focuses more on asset management.
- R&D model differs greatly from that of a decade ago. It is multi-disciplinary and requires an ability to collaborate and partner.
- Another characteristic of the emerging models is that there is explicit consideration about investment, risk, and knowledge.

Global life sciences industry issues in 2014

Complying with regulatory changes

Government policies and mandates

- The U.S. FDA, Europe's EMA, the Brazilian National Medicines Agency (ANVISA), and Mexico's Federal Commission for Protection against Health Risks (COFEPRIS) are among the scores of government agencies that regulate life sciences product approvals.

- The agencies investigate and litigate alleged fraud violations, product quality issues, corruption, and improper sales activities such as off-label promotion of drugs or improper contact with physicians.

- Each country develops and enforces its own regulations, such as the U.K. Bribery Act, and the U.S. Physician Payments Sunshine Act and the Foreign Corrupt Practices Act (FCPA), increasing numbers of countries are enhancing cross-border agency collaboration to strength regulatory decision making and enforcement actions.

Global life sciences industry issues in 2014

Navigating global health care reform

Cost containment

- It is a common reform objective in both developed and developing markets.
- Most national health care systems have been encouraging greater use of generic drugs.
- Germany and several other countries have turned to value-based pricing for new drugs.
- Some countries are increasingly mandating prices.

Medical and life sciences product innovation

- China has identified biotechnology as one of seven strategic industries in its latest five-year reform plan.
- Brazilian government is in the midst of a ten-year biotechnology development program.
- U.K. has reduced taxes on exploiting British-owned intellectual property.

Improving health care access

- Expanding insurance coverage to millions of consumers around the globe.
- Increasing governments' direct purchase of life sciences products.

Global life sciences industry issues in 2014

Complying with regulatory changes

Drug safety

- Drug safety standards — particularly those associated with quality systems implementation, data integrity, and validation of processes in manufacturing or testing — continue to tighten in countries around the world.

- Some pharmaceutical companies are also taking voluntary steps to advance drug safety measures.

- Others are investing in robust, long-term cleansing and archiving of data for compliance purposes and promote ongoing oversight through regular review of KPIs.

- Certain countries struggle with drug safety issues more than others.

- Pharmaceutical companies have experienced regulatory actions, including drug recalls, warning letters, and penalties from the FDA for violating U.S. rules such as lapses in good manufacturing practices.

Global life sciences industry issues in 2014

Complying with regulatory changes

Counterfeiting

- World Health Organization (WHO) estimates range from around one percent of sales in developed countries to over 10 percent in developing countries, depending on the geographical area.

- Weak or incomplete supply chain security — particularly when many supply chains are expanding across the globe — is exacerbating the spread of counterfeit drugs, particularly in emerging markets.

- Legislation such as the EU's Falsified Medicines Directive (FMD) has been enacted with the goals of reducing counterfeit products and bringing some transparency to the parallel trade.

Global life sciences industry issues in 2014

Complying with regulatory changes

M&A and joint ventures

- Increasingly, life sciences companies are conducting M&A and JV transactions or have key third-party contractual relationships in emerging markets.

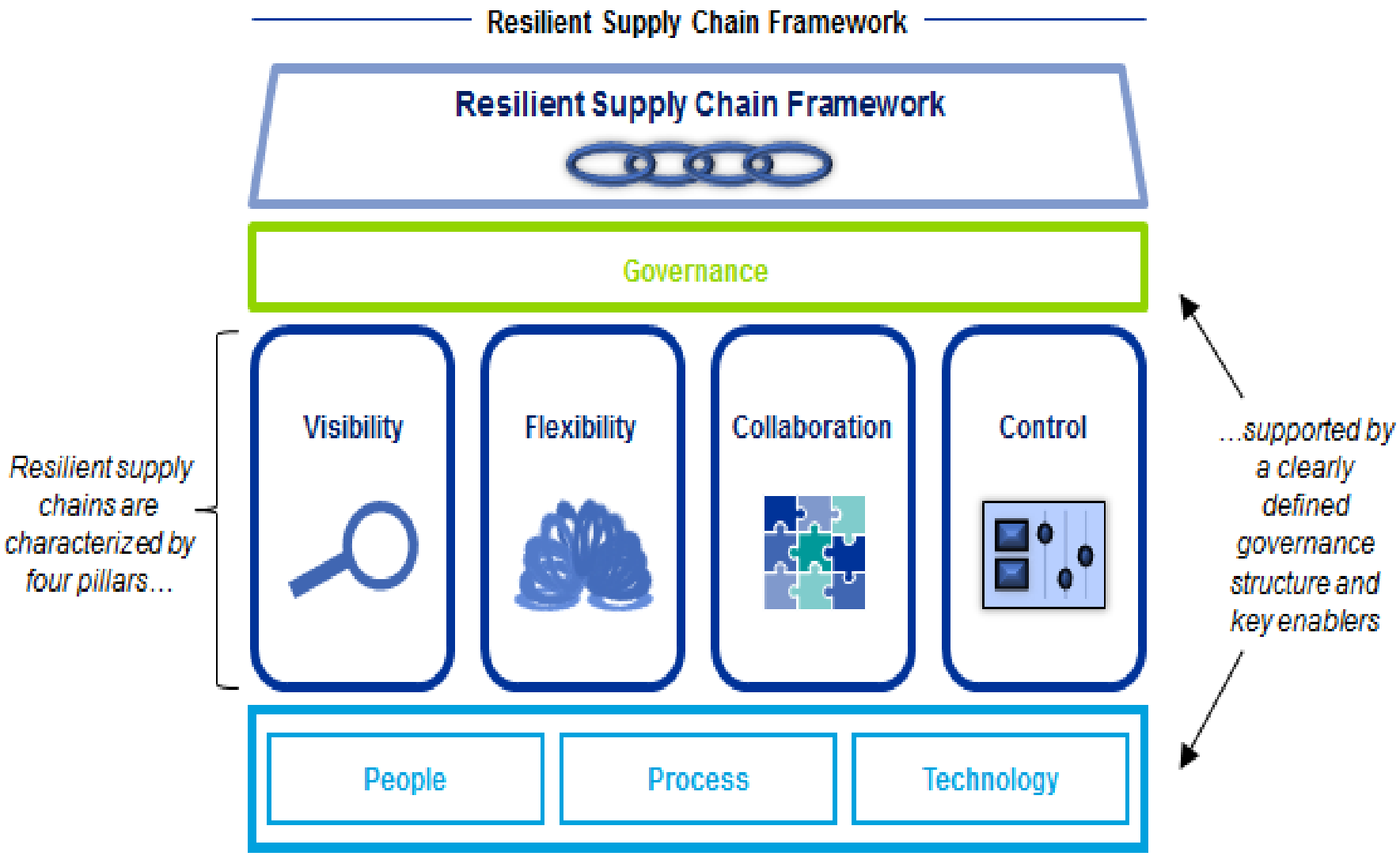
- Among potential concerns are the quality and veracity of financial information; lack of infrastructure and substantive controls; inadequate reporting of liabilities; unclear legal title of assets; and questionable local governance and operational practices.

- However, all local representatives should be thoroughly vetted to avoid FCPA issues. Important watch words: Know the relationship; know the partners.

Supply chain is one of the big areas of focus

- Sustainability on the agenda
- Supply security
- Supply Chain Risk
- Reputational risk
- Compliance risk

Building Resilience into the Supply Chain



New Business Models: Health Data is transforming what is possible

Supply Drivers

Increasing 'possibilities' through health data

Medical & patient data

EHRs, HIEs, health sensors, social media, and genomics are creating rich new data sources ready for analysis

Big data analytics

Cheap computing power and sophisticated analytics are driving ways to create insights into **patient behavior**, treatment **costs** and in **R&D**

Mobile / mHealth

Pervasive mobile and smart phone adoption creates **new engagement models within daily routines**

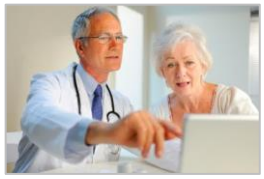
HCP Digital workflow

Increasing integration of **EHRs and telehealth** driving new digitally-enabled coordinated care models

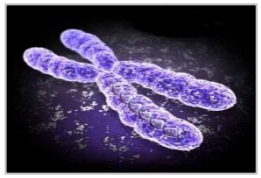
HIT enabled opportunities

Demand Drivers

Intensifying need to address cost & quality



Aging patients, in-home treatment, mobile reduce medical errors and **improve quality**



Discover and deliver **targeted and personalized therapies** with **real world evidence** of impact

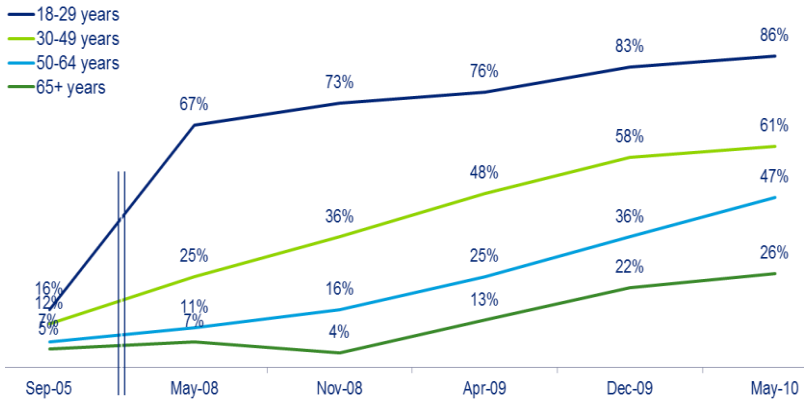
Influence **patients behaviors "beyond the pill"** and sustain **engagement outside the traditional care setting**

Drive **population management, protocol driven care**, and data driven **patient risk pool management**

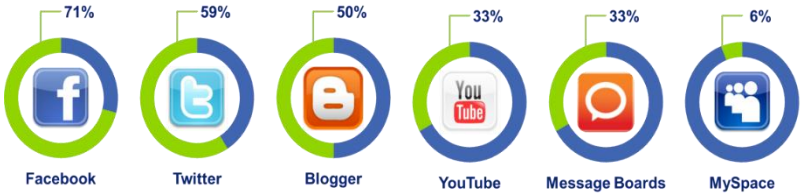
Social Media Use Continues to Expand

Pharma companies are increasingly building their presence in Social Media channels

US Users of Social Media (1)



Companies Using Social Media (1)

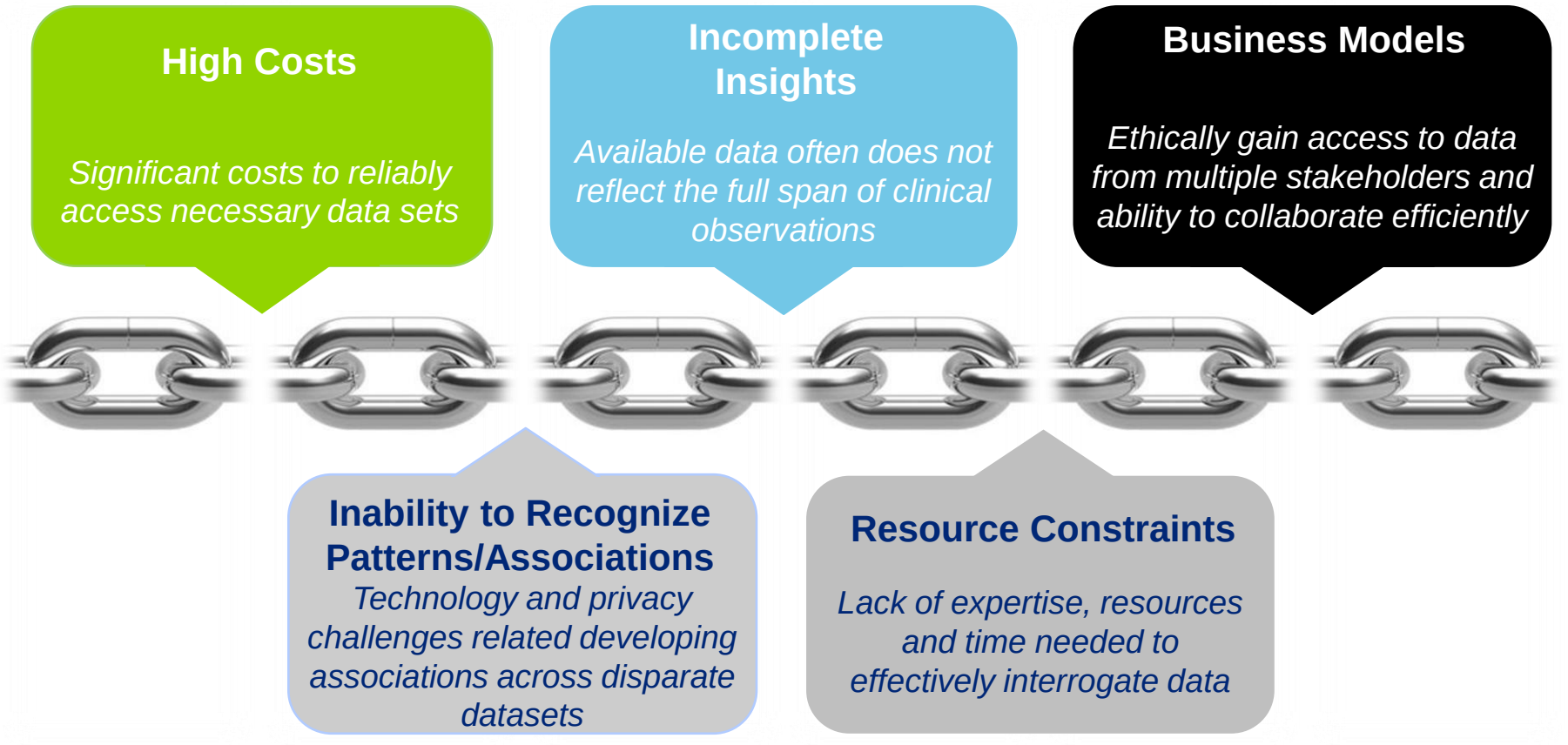


Pharma Presence in Social Media (2)

Pharmaceutical	Facebook	Twitter		YouTube	
Company	Page	Followers	Tweets	Videos	Views
Johnson & Johnson	Yes CE	9,516	1,904	599	4,959,881
Pfizer	Yes CE	20,068	561	30	10,644
Roche	No	13,576	1,502	?	?
GlaxoSmithKline	Yes CE	9,940	468	45	61,001
Novartis	Yes	17,054	932	6	238,615
Sanofi-Aventis US	Yes CE	1,691	1,149	51	110,514
AstraZeneca	Yes CE	9,169	534	26	12,147
Abbot Labs	Yes	875	0	?	?
Merck	Yes CE	1,698	64	3	859
Bayer US	Yes CE	2,357	536	66	59,054
Eli Lilly	Yes	5,444	1,378	22	4,114
Bristol-Myers	Yes	5,863	269	?	?
	Comments Enabled (CE); Page not Found (?)				

(1) Source: The Growth of Social Media: An Infographic;
http://www.searchenginejournal.com/the-growth-of-social-media-an-infographic/32788/
(2) Source: Pharma's Social Media Experiments Tap Enthusiasm, Await Regulatory Guidance;
http://www.searchenginejournal.com/the-growth-of-social-media-an-infographic/32788/

Life Sciences decision makers are confronted with data and analytics issues



Successful use of data requires: 1) widespread and easy accessibility to existing data and evidence assets, 2) clinical nuances and background to derive insights from data, 3) near real-time connectivity to health systems to further build on that evidence, and 4) appropriately skilled resources to do the same

Global life sciences industry issues in 2014
Technology

Technology advancements

- Technology advances are connecting developed and emerging markets — and participants along the health care and life sciences value chain.

- Adoption of new digital health information technologies (HIT) such as electronic medical records (EMRs), telemedicine, and mobile health (mHealth) applications, and electronic medical prescriptions is driving change in the way physicians, patients and other sector stakeholders interact.

- Increasing use of M&A, JVs and other collaborative business models means that companies with disparate systems will need to synergize their local operations with global requirements.

- Top pharma manufacturers are focusing on optimizing their IT investments, concentrating their efforts on facilitating real-time communication and visibility between the R&D and marketing sectors.

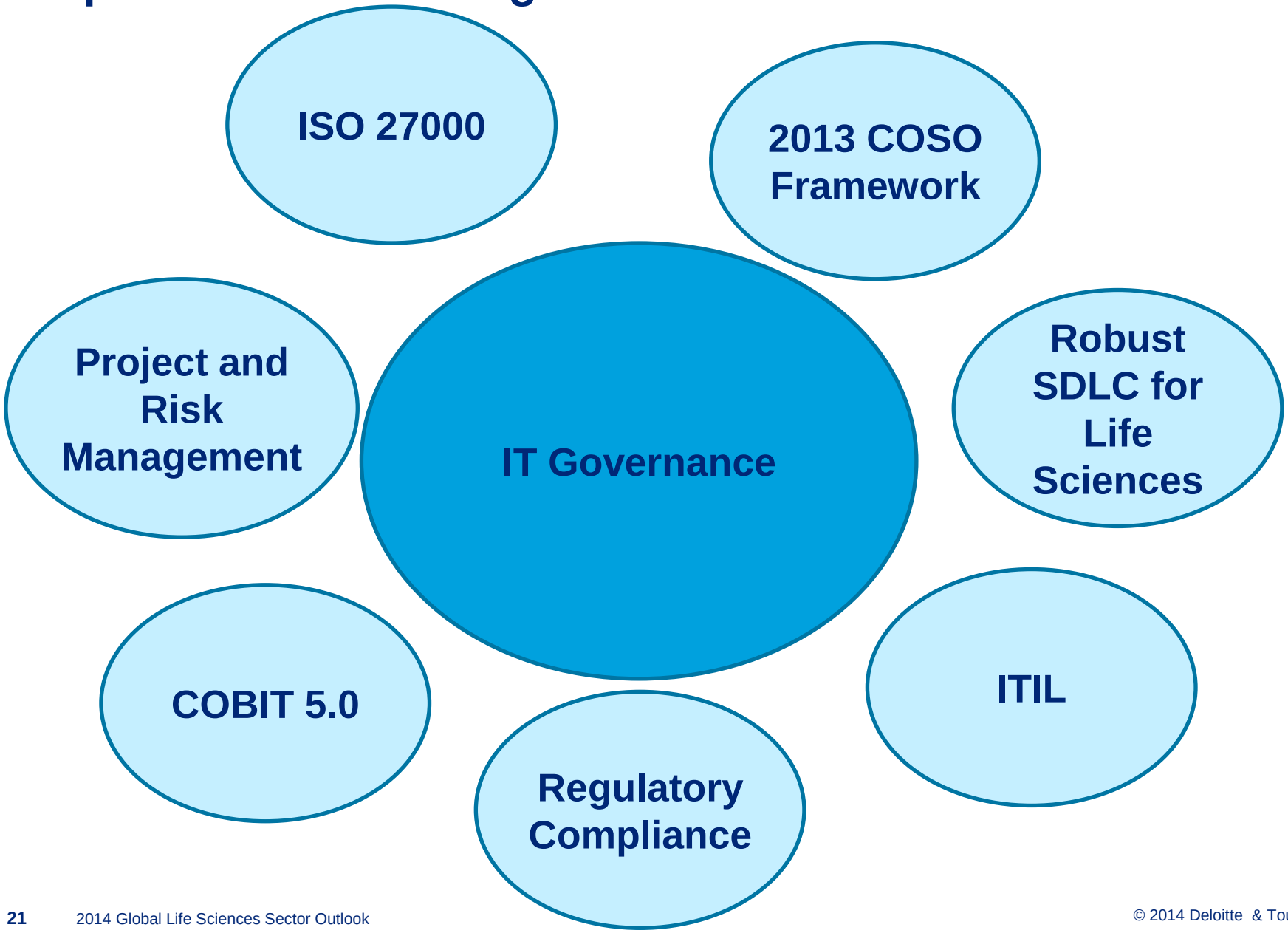
Global life sciences industry issues in 2014

Complying with regulatory changes

Information security and privacy

- Life sciences companies in the sector are increasingly challenged to protect their intellectual property (IP) and other valuable intangible assets.
- Networked medical devices and other mobile health (mHealth) technologies may expose patients and health care provider organizations to safety and security risks.
- Increased government focus on information security and privacy is most evident in the United States. FDA regulations on Unique Device Identifier
- Complex and outsourced Supply Chains need to be secure. Regulations are changing around packaging, serialization, track and trace.
- Potential patient safety, economic and reputational damage may arise if organizations lack appropriate security and privacy controls, lost productivity and other costs, brand and reputational loss, and loss of consumer goodwill, among others.
- On the other hand – there are opportunities for companies that are excellent in these areas and can prove themselves to be best in class.

Requirement for Strong IT Governance

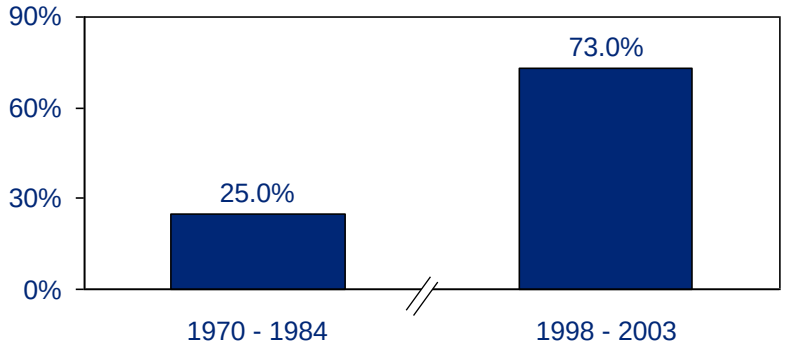


Healthcare authorities are becoming more risk-averse and demanding higher requirements for safety and efficacy

Post-Marketing Monitoring

- FDA is emphasising pharmacovigilance, and **require companies to monitor the safety of their products in the market**

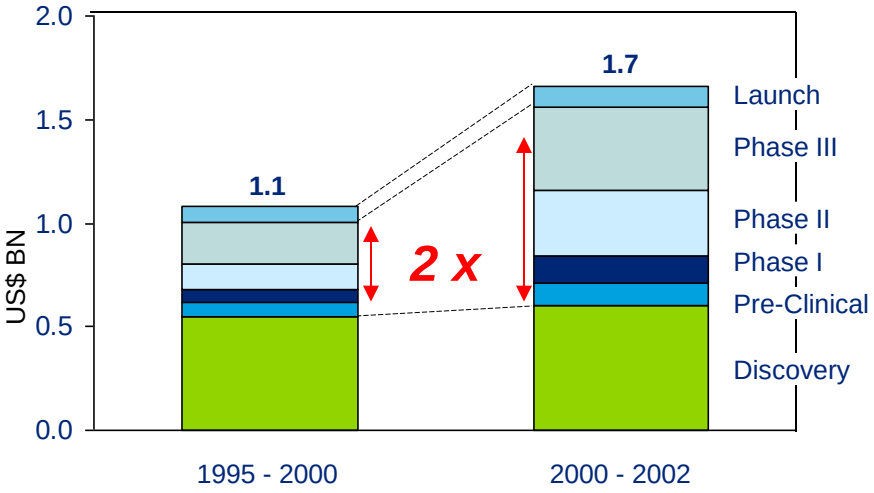
% of FDA approved drugs requiring post marketing monitoring (1970 - 2003)



Expanded Clinical Trials

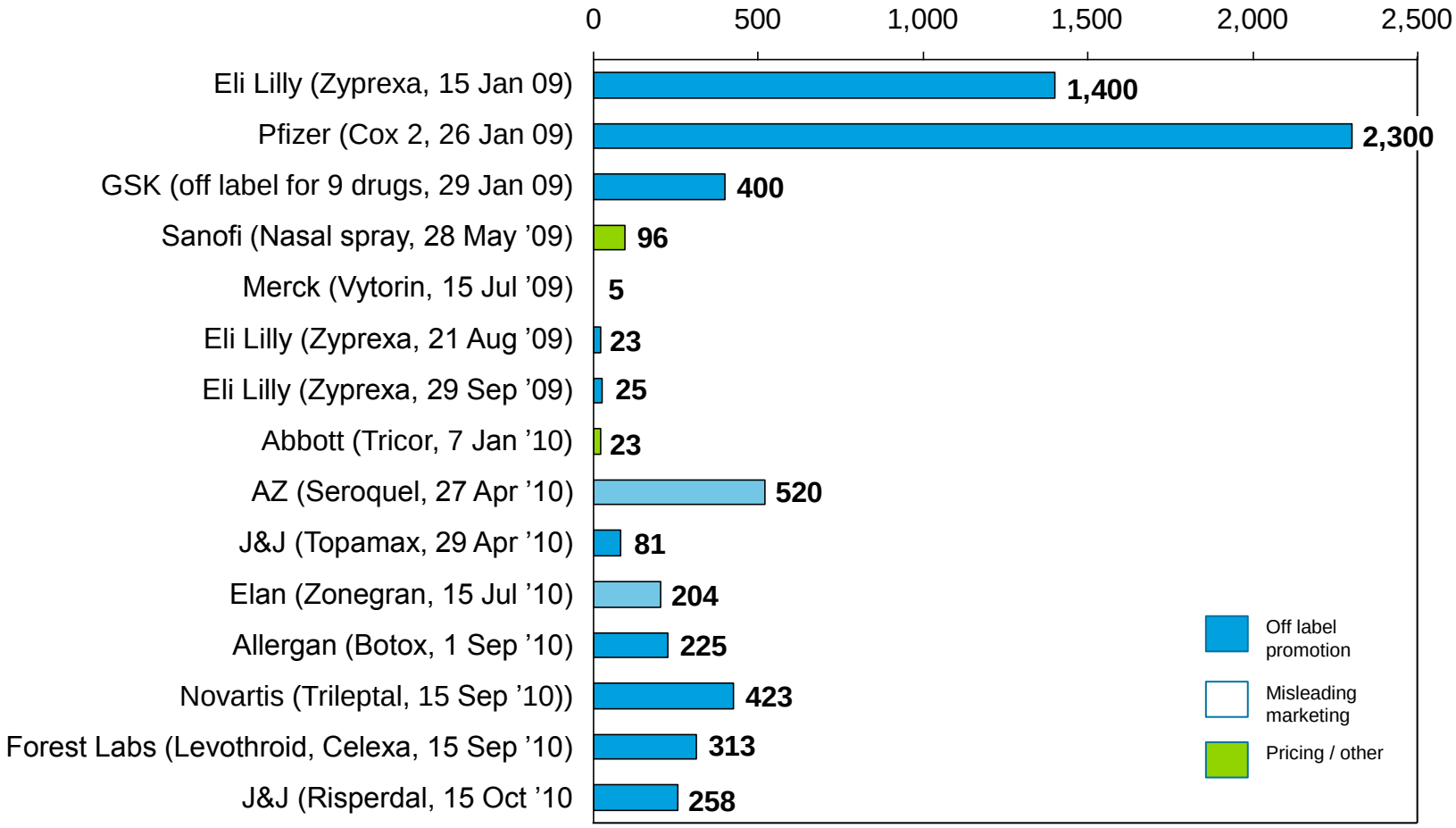
- Regulatory demands are increasing
  - **Expanded clinical trials and larger databases**
  - More **diverse sub-populations** to prove therapeutic improvements over existing substances
- **Increased in the cost of clinical trials**

Cost Breakdown for Launching a New Drug (1995 - 2002)



Source: EFPIA Position Paper (Nov2004); In Vivo Business & Medical Report (Nov 2003)

More than $6bn of penalties for off label selling in 2009/10 focused pharma on compliance



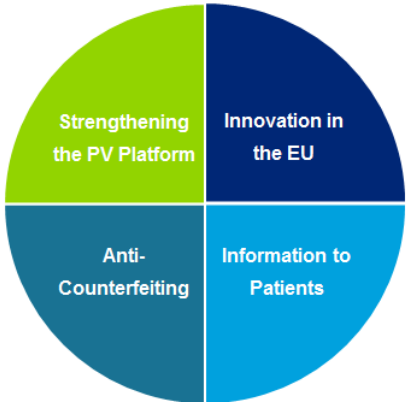
Source: Fierce Pharma

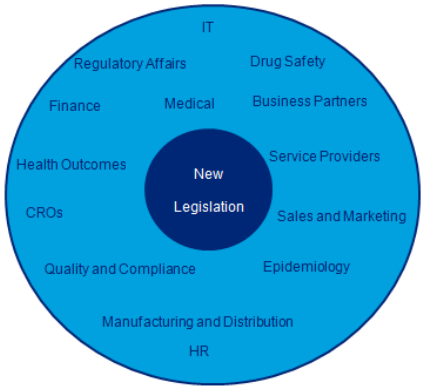
A tougher game: Example of New EU Pharmacovigilance Legislation

New Good Vigilance Guidelines - GVP

Submission of Medical Product data

Improved data formats/interoperability for data transmission and exchange





Industry Perspective - Departments Impacted

New PV Legislation Regulators require:

- Significant increase and **transparency** into medicinal product data
- Better **quality** medicinal product data to be submitted
- Increased scrutiny on the **benefit risk** of medical products
- Increased **monitoring** of products
- Increased global **interoperability** and **collaboration**, new submissions formats/data
- Faster decision making

Impact on Pharma:

- Impacts all companies whom market products and/or who sponsor clinical trials within the European Union
- **New data requirements** of the agencies will create a new era of increased collaborations
- Changes are **cross functional** in nature and will impact multiple departments not just R&D
- **Additional head count** required to comprehend and implement the changes
- **Consolidation** of data is necessary from disparate systems and processes
- Additional Solutions/tools required

Lack of transparency has contributed to increased use of RWD

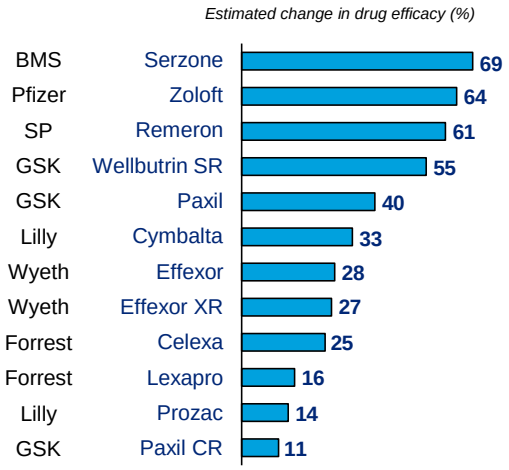
Lack of transparency over drug safety…

Example Controversies[1]

- **GSK:** $3bn settlement over undisclosed safety data relating to Avandia, Wellbutrin & Paxil
- **Merck:** Vioxx estimated to have caused 80-140k heart attacks. 190 class actions filed against the adequacy of safety warnings (>$5bn set aside for settlement)
- **Wyeth:** Pondimin withdrawn after it was shown to cause potentially fatal pulmonary hypertension and heart valve problems leading to $13bn in legal damages

…and product efficacy…

Estimate of how much drug impression was inflated by not publishing unfavorable studies[2]



…has led to increased scrutiny and use of RWD

EU measures to increase scrutiny[3]

- Under VBP, post launch outcomes could support revisions of price
- Under AMNOG, product prices will be reassessed post launch using RWD
- Use of RWD will become a requirement to ensure continued market access and ANSM now has the right to demand comparative data

Note: 1) Press; 2) New England Journal of Medicine; 3) IMS Health 2011

EU Regulatory landscape

New medical device regulations in Europe will be finalized soon

EU Medical Devices Directives (MDD) and in vitro Diagnostics Directive (IVDD)

European Medicines Agency and FDA announce launch of generic medicines application inspections initiative

Regulation Vs Innovation - "A Challenging Balancing Act"

- Some regulatory agencies are now grappling with ***how to strike the right balance between promoting innovation and ensuring safety***

- Some indications that the FDA are now attempting to adopt a more flexible approach

- In order to function optimally the regulatory system has to find the right balance in three key areas:

  1. **Cautiousness**
  2. **Incentive structure**
  3. **Comprehensiveness**

Global life sciences industry issues in 2014
Final considerations

Regulatory compliance

- Executives at many life sciences companies are deciding that it is worth pursuing stronger compliance risk management capabilities for their own sake, rather than to merely satisfy emerging legal requirements.

- They are re-evaluating their organization's entire approach to managing compliance risks, applying many of the methodologies used for financial reporting to compliance issues.

- Taking a risk-based approach to compliance planning, execution, and monitoring makes good business sense in a heightened regulatory environment.